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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,596	09/14/2001	Severine Bousquet	BDL-360XX	8717
207	7590	05/05/2005	EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			MCKANE, ELIZABETH L	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/936,596	BOUSQUET, SOUVERINE ET AL
	<b>Examiner</b>	<b>Art Unit</b>
	Leigh McKane	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-57 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-57 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>091402</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18, 30, 36, 46-49, 52, 56, and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 18 and 52, “a second relative humidity sensor” is vague and indefinite as no “first” humidity sensor has been claimed.

As to claims 30 and 52, the terminology “of limited usage” renders the claim vague and indefinite because it is not clear how this phrase structurally limits the claim.

Claim 36 is confusing because the plasma generation region is incorporated into the object to be treated. However, claim 13, from which this claim depends, requires that the plasma generation region be separate from the sterilization region. If the object to be treated is located within the sterilization region, how can the plasma generation region be incorporated into the object?

With respect to claims 46-49, 56, and 57, attempts to claim a process without setting forth any steps involved in the process, render the resulting claim indefinite. See *Ex parte Erlich*, 3 uSPQ2d 1011 (Bd. Pat. Appl. & Inter. 1986).

***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 46-49, 56, and 57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The above claims attempt to claim a process without setting forth any active, positive steps delimiting how this process is actually practiced. As a result, these claims are improper definitions of a process. See *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacob (U.S. Patent No. 5,200,158).

Jacob teaches a process for plasma sterilization wherein an object to be treated is placed in a treatment chamber at atmospheric pressure, before the plasma is created or during treatment (col.13, lines 22-24). A gas such as ambient air (col.4, lines 39-63) containing water vapor (col.3, lines 36-39) is continuously introduced into the chamber and a plasma generated using a high voltage electrode and an earth electrode (see Figures). The gas flow rate is controlled (col.15, lines 47-51) and a pump may be used. The plasma is generated between the electrodes

and carried to the object to be treated. After treatment, the plasma is removed from the chamber. See col.4, lines 11-29. The water vapor, which has been added to the gas, can be added in the interelectrode region (as in Figure 5) or directly around the object (as in Figure 10) depending upon the electrode arrangement. The relative humidity is maintained at 50-60% (col.13, lines 38-41).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 7, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacob.

As set forth above, Jacob discloses using ambient air (which contains at least 10% oxygen and 10% nitrogen) as the gas. Moreover, Jacob teaches that the presence of water vapor enhances sterilization efficiency dramatically. Although Jacob discloses a preferred relative

humidity of between 50 and 60%, it is deemed obvious to one of ordinary skill in the art to increase the relative humidity as desired based upon operating parameters.

10. Claims 13-40, 46, 47, and 49-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-211263 in view of Jacob.

JP 10-211263 teaches a first gas source **18** containing a non-biocidal gas mixture, a treatment chamber **50** at atmospheric pressure (before plasma sterilization), a plasma generation region **12** separate from the sterilization region, a high voltage electrode **40**, an earth electrode **38**, and an exhaust gas processor **28**. First gas source is mixed with gas from second source **14** and humidified downstream by **44**. Although Jacob does not teach maintaining the treatment chamber at atmospheric pressure during treatment, Jacob evidences that this is a desirable environment (col.13, lines 22-58). As treatment at atmospheric pressure doesn't require the use of expensive pressure vessels, it would have been an obvious modification to the invention of JP 10-211263.

Moreover, it is not deemed inventive to mix the ambient air with the inert gas as the results are not unexpected.

JP 10-211263 fails to teach use of a humidity sensor. However, Jacob discloses that it is known in the art to maintain the humidity of a plasma sterilization chamber between 50-60% to improve sterilization efficiency. Since it would have been obvious to improve sterilization efficiency of JP 10-211263, one would have found it obvious to use a known means of monitoring humidity, such as a humidity sensor, and to place them at various locations through the system. Such sensors are well-known in the art.

The gas used by JP 10-211263 may be ambient air, which contains at least 10% oxygen and 10% nitrogen. See machine translation, page 4, paragraph [0026], which may be compressed.

The electrodes used by JP 10-211263 for plasma generation include a metal, cylinder electrode **38** having a large radius of curvature and a metal, wire electrode **40** with a small radius of curvature. The electrodes may have a dielectric coating. See machine translation, page 3, paragraph [0018]. The electrodes generate the plasma using a pulse voltage.

Although JP 10-211263 is silent with respect to an array of parallel electrodes, Jacob evidences an array of parallel electrodes (Figure 10). In order to increase the amount of plasma produced and/or the amount of material to be treated, it would have been obvious to arrange the electrodes of JP 10-211263 in the parallel array of Jacob. Similarly, it would have been obvious to increase the number of treatment chambers, thereby increasing the amount of material to be treated in given time period.

JP 10-211263 fails to teach a treatment chamber having a shape or support specially tailored to the object being treated. However, Jacob discloses that this was known in the art. See Figures 11-14; col.14, lines 23-31; and basket **25**. As such chambers reduce waste of the sterilant species and improve sterilization efficiency, it would have been obvious to modify the chamber shape of JP 10-211263 to the object being treated.

11. Claims 41-45, 53, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-211263 and Jacob as applied to claim 32 above, and further in view of Kirckof et al (U.S. Patent No. 6,485,978).

The combination above fails to teach indicating and control means or printing means.

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However, such is known in the art of sterilization. Kirckof et al discloses a control means for a sterilizing process wherein labels containing indicator barcodes are used to chemically monitor the sterilization cycle and subsequent movement of the sterilized articles. A computer and printer monitor and dispense reports. See Abstract; col.19, line 49 to col.20, line 24. As tracking of sterilized articles is known in the art, it would have been an obvious addition to the invention of the combination in order to provide accurate reporting of the location and authenticity of sterilized items.

12. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-211263, Jacob, and Kirckof et al as applied to claim 45 above, and further in view of Hammerstrom et al (U.S. Patent No. 6,455,014).

The combination *supra* is silent with respect to using the plasma to decontaminate the internal surface of air conditioning systems. Hammerstrom et al teaches that it was known in the art at the time of the invention to use a plasma to decontaminate the internal surfaces of air conditioning systems (col.7, lines 32-47). As plasma has been shown to be effective in the decontamination of air conditioning systems, it would have been obvious to employ the plasma generated by JP 10-211263 to such a purpose.

13. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-211263 and Jacob as applied to claim 13 above, and further in view of Hammerstrom et al.

The combination *supra* is silent with respect to using the plasma to decontaminate the internal surface of air conditioning systems. Hammerstrom et al teaches that it was known in the art at the time of the invention to use a plasma to decontaminate the internal surfaces of air conditioning systems (col.7, lines 32-47). As plasma has been shown to be effective in the

decontamination of air conditioning systems, it would have been obvious to employ the plasma generated by JP 10-211263 to such a purpose.

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sanka et al (U.S. Patent No. 5,696,686) teaches an automated system for monitoring sterilization process data.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (6:30 am-4:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Leigh McKane*  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
2 May 2005